SEP - 7 2005

510(K) SUMMARY

Subject 510(k) Number ***K050388***

Sponsor

Xtremi-T, LLC

3131 Princeton Pike
Bldg 5, Suite 200
Lawrenceville, New Jersey 08648

FDA Establishment Registration Number

3004613836

Official Contact

Shawn T. Huxel, President
Xtremi-T, LLC
3131 Princeton Pike; Bldg 5, Suite 200
Lawrenceville, New Jersey 08648
Phone - (609) 896-0008
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Proprietary Name

ReFIX™ Internal Fixation Screws

Common Name

Biodegradable Internal Fixation Device

Classification Name and Reference

888.3040 – Smooth or Threaded Bone Fixation Fastener

Regulatory Class

Class II

Device Product Code

(Panel 87) HWC

Date Prepared

25 April, 2005

Brief Description of Device

ReFIX™ Screws are comprised of Internal Fracture Fixation Devices based upon biodegradable polymer fixation systems. Biodegradable polymers are widely used in the orthopaedic specialty. The ReFIX Screws are manufactured from PLLA and PLGA. The Screws are available in diameters ranging from 2.7mm to 6.0mm. ReFIX Screws are available in lengths ranging from 30mm to 60mm. The Screws are sized and trimmed intraoperatively using the ReFIX instrumentation according to the surgical technique. The sizes and materials are designed to address the indications cited.

Indications for Use

ReFIX Screws are intended for use in the fixation and/or alignment of fragments of fractured non-load bearing bones, osteotomies and arthrodeses; and fixation and/or alignment of apical fragments, osteochondral fragments cancellous/non-load bearing bone fragments.

For example, ReFIX Screws are intended for use in fractures of the ankle, colles, distal radius, hand and wrist, humeral condyle, malleolus, metacarpals, olecranon, phalanges and the radial head; fusions of metacarpals, metatarsals and phalanges; and correction of hallux valgus.

Basis for Substantial Equivalence

The substantial equivalence of the ReFIX Screws is based on the equivalence in intended use, materials, operational principals, and indications to:

DEVICE	Manufacturer	Trade Name
K041189	Arthrex	TRIMIt
K992301	Biomet	Reunite Screw
K964970	Biomet	Bonescrew
K042295	Bionx	Smartscrew
K032447	Bionx	Nugen FX
K023022	Bionx	Nugen FX
K012001	Bionx	Smartscrew
K003077	Bionx	Smartscrew
K992947	Bionx	Smartscrew
K974876	Bionx	Distal Radius Screw
K030900	Inion	OTPS System
K023887	Inion	OTPS System

END OF 510(K) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2005

Mr. Shawn T. Huxel
President
Xtremi-T, LLC
3131 Princeton Pike
Building 5, Suite 200
Lawrenceville, New Jersey 08648

Re: K050388
Trade/Device Name: ReFIX™ Internal Fracture Fixation Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 18, 2005
Received: July 19, 2005

Dear Mr. Huxel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain. other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510 (K) NUMBER IF KNOWN: K050388

MANUFACTURER: Xtremi-T, LLC

DEVICE NAME: ReFIX Internal Fracture Fixation Screws

Indications:

ReFIX Screws are intended for use in the fixation and/or alignment of fragments of fractured non-load bearing bones, osteotomies and arthrodeses; and fixation and/or alignment of apical fragments, osteochondral fragments and cancellous/non-load bearing bone fragments.

For example, ReFIX Screws are intended for use in fractures of the ankle, colles, distal radius, hand and wrist, humeral condyle, malleolus, metacarpals, olecranon, phalanges and the radial head; fusions of metacarpals, metatarsals and phalanges; and correction of hallux valgus.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes **or** **Over-the-Counter Use** No

(Per 21 CFR 801.109) (Optional Format 1-2-1996)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050388